

NOV 4 1998

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**for the**  
**CADD-Legacy™ 1 MODEL 6400 AMBULATORY INFUSION SYSTEM**

**I. GENERAL INFORMATION**

Common/Usual Name: Ambulatory Infusion Pump

Proprietary Name: CADD-Legacy™ 1 Model 6400  
Ambulatory Infusion System

Applicant's name and address: SIMS Deltec, Inc.  
1265 Grey Fox Road  
St. Paul, MN 55112

Equivalence device comparison: CADD-1® Ambulatory Infusion Pump and  
CADD-Prizm® VIP Model 6100 Ambulatory  
Infusion System

**II. DEVICE DESCRIPTION**

The CADD-Legacy™ 1 Model 6400 ambulatory infusion pump is similar in design, function, and intended use to Deltec's CADD-1® Ambulatory Infusion Pump and the CADD-Prizm® VIP Model 6100 Ambulatory Infusion System. The Model 6400 pump provides measured drug therapy for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space or subarachnoid space delivery to patients in hospital or outpatient settings. The pump is capable of storing one delivery application. The delivery application resident in the Model 6400 pump and the subject of this 510(k) Notification is the continuous delivery application.

**III. ALTERNATIVES**

Alternatives to the CADD-Legacy™ 1 Model 6400 pump include the use of other commercially available ambulatory infusion pumps, such as Deltec's CADD-1® and CADD-Prizm® VIP Ambulatory Infusion Pumps.

**IV. POTENTIAL ADVERSE EFFECTS**

The potential direct adverse effects that may occur when using the CADD-Legacy™ 1 Model 6400 pump, as well as other commercially available non-implantable ambulatory infusion pumps, include the possibility of over-infusion, under-infusion, or no infusion.

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**V. SUMMARY OF STUDIES**

**A. Functional Testing**

Test plans associated with software validation, verification of software controlled programming functions, and software related to proper pump operation were certified for the CADD-Legacy™ 1 Model 6400 Ambulatory Infusion System.

**B. Clinical Studies**

Clinical studies were not deemed necessary regarding the use of the CADD-Legacy™ 1 Model 6400 Ambulatory Infusion System.

**VI. CONCLUSIONS DRAWN FROM THESE STUDIES**

Based upon the information provided above, the CADD-Legacy™ 1 Model 6400 Ambulatory Infusion System is substantially equivalent to other commercially available ambulatory infusion systems.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 4 1998

Mr. Edward W. Numainville  
Vice President, Regulatory Affairs and Quality Systems  
SIMS Deltec, Incorporated  
1265 Grey Fox Road  
St. Paul, Minnesota 55112

Re: K982838  
Trade Name: CADD-Legacy™ 1 Ambulatory Infusion  
System, Model 6400  
Regulatory Class: II  
Product Code: FRN  
Dated: August 12, 1998  
Received: August 12, 1998

Dear Mr. Numainville:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

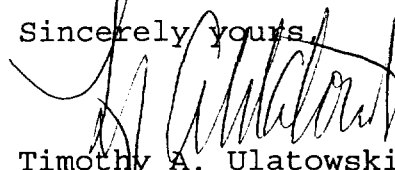
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number  
(if known): \_\_\_\_\_

Device Name: CADD-Legacy™ 1 Model 6400 Ambulatory Infusion Pump

Indications For Use:

**“The CADD-Legacy™ pump is suitable for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space, or subarachnoid space infusion.”**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1/2/96)

Patricia Cucenite  
(Division Sign-Off)

Division of Device, Infection Control,  
and General Hospital Devices

510(k) Number K982838